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10/538,150	06/08/2005	Sharon Katrina Watson	05-470	1497
20306 7590 03/15/2010 MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606				
EXAMINER				
LEE, JOHN W				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,150

Applicant(s)

WATSON ET AL.

Examiner

JOHN Wahnkyo LEE

Art Unit

2624

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 19, 21, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20, 22 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

- The application was forwarded to the examiner on 8 January 2010.

Response to Arguments/Amendments

1. Applicant's arguments and amendments filed on 30 December 2009 have been fully considered.
2. Applicant's response to claim objection has been considered. The objection has been withdrawn as the claim was converted to an independent claim.
3. Applicant's argument, with respect to claims 1-18 and 22 under 35 U.S.C. 101, has been considered, and it is persuasive. The rejection has been withdrawn.
4. Applicant's arguments, with respect to claims 1-18, 20, 22 and 25, under 35 U.S.C. 112, first paragraph, have been considered. The arguments are not persuasive. "Defining respective regions of specified extent within the image around said locations" is not supported or disclosed by the original specification. Page 10, line 25- page 11, line 2 discloses local regions of interest (ROI) are defined, but not regions being specified of specified extent. This part of the specification merely discloses that ROI has an extent of 50 pixels, not a specified extent. Furthermore, the specification also discloses defining by taking the regions identified in stage 22, which does not really supports defining respective regions of specified extent. Claims are reciting a claim limitation, which is narrower and more specific than the original specification. However, this is not over yet. Page 10, line 25-page 11, line 2 discloses defining regions of extent with the image around or surrounded with the objects, not just the location. The

examiner does not truly understand why the applicant had amended this claim limitation by changing it from the object to location in the previous responses, which can raise a 112, first paragraph issue. Figures 3 and 4 explained in page 13, line 25-page 14, line 17 does not support this claim limitation as well. Examiner also noticed that the applicant amended the paragraph of page 10, line 25 of the original specification by adding words such as "specified" and "given a specified extent," which changes the scope of the original specification. An objection will be given to the specification for this reason. So, the rejection cannot be withdrawn.

5. Applicant's arguments, with respect to claims 1-18, 20, 22 and 25, under 35 U.S.C. 112, second paragraph, have been considered. The applicant argument is not persuasive. There are still lack antecedent basis all over the claim limitations. In claim 1, the claim limitation (a) was amended by adding objects. However, "objects" has been used right after the "locations", so the proper way to amend it would have been "said objects" or "the object." Because it is not clear the "objects" is a new key term of the claim limitation or trying to refer the "objections" right after "the locations." Same reason applies to claim limitation (c). "Respective said regions" should have been "the respective regions" or "said respective regions". It is also same for claim limitation (d). "One respective said contours" should have been "said one or more respective closed contours" or "the one or more respective closed contours"; "respective said region" should have been "the respective region" or "said respective region." Rests of the claims are rejected for the same reason with claim 1.

6. Applicant's arguments, with respect to claims 1-18, 20, 22 and 25 under 35 U.S.C. 103 (a), have been considered but are moot in view of the new ground(s) of rejection. A detail rejection will be provided below.

Specification

1. The amendment filed 30 December 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the applicant amended the paragraph of page 10, line 25 of the original specification by adding words such as "specified" and "given a specified extent," which changes the scope of the original specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

2. Claims 26-27 are objected to because of the following informalities: The claim is not clear whether it is an independent or a dependent claim. The examiner requires the applicant to rewrite claim 25 that can be consistent with the other claims. Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 25 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 25 defines a compute program. The specification indicates that the embodiment can be implemented by a pure coding of a computer program in page 22, lines 6-9. Therefore, the claim as a whole appears to be nothing more than software, which makes the claim non-statutory as software per-se.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-18, 20 and 22, 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. "Defining respective regions of specified extent within the image around said locations" is not supported or disclosed by the original specification. Page 10, line 25- page 11, line 2 discloses local regions of interest (ROI) are defined, but not regions being specified of specified extent. This part of the specification merely discloses that ROI has an extent of 50 pixels, not a

specified extent. Furthermore, the specification also discloses defining by taking the regions identified in stage 22, which does not really supports defining respective regions of specified extent. Claims are reciting a claim limitation, which is narrower and more specific than the original specification. However, this is not over yet. Page 10, line 25-page 11, line 2 discloses defining regions of extent with the image around or surrounded with the objects, not just the location. The examiner does not truly understand why the applicant had amended this claim limitation by changing it from the object to location in the previous responses, which can raise a 112, first paragraph issue. Figures 3 and 4 explained in page 13, line 25-page 14, line 17 does not support this claim limitation as well. Moreover, claim 1 has a limitation added "using a computer or processor to perform." However, the specification indicates that the embodiment can be implemented by a pure coding of a computer program in page 22, lines 6-9. There is no part of the specification discloses using a computer, a processor, or even some type of computer parts. The same reasons also apply to claims 2-18, 20, 22 and 26-27.

7. Claims 1-18, 20 and 22 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, "using a computer or processor to perform the successive steps," which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-18, 20, 22 and 25-27 have insufficient antecedent basis in the claims.

Regarding claim 1, the claim limitation (a) was amended by adding objects. However, "objects" has been used right after the "locations", so the proper way to amend it would have been "said objects" or "the object." Because it is not clear the "objects" is a new key term of the claim limitation or trying to refer the "objections" right after "the locations." Same reason applies to claim limitation (c). "Respective said regions" should have been "the respective regions" or "said respective regions". It is also same for claim limitation (d). "One respective said contours" should have been "said one or more respective closed contours" or "the one or more respective closed contours"; "respective said region" should have been "the respective region" or "said respective region." Rests of the claims are rejected for the same reason with claim 1.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-14, 17-18, 20, 22, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Netsch et al. ("Scale-Space Signatures for the Detection Clustered Microclacifications in Digital Mammograms") in view of Madachy et al. ("Image Analysis For Automatic classification of mitotic cervical cells").

Regarding claim 1, Netsch teaches a method for the automated analysis of a digital image comprising an array of pixels (Chapter III. section A.; page 776, "image pixels") including the successive steps of: (a) identifying the locations of objects (Chapter III. section A.; page 776, "circular spots") within the image which objects have specified intensity (Chapter III. section A.; page 776, "local contrast C") and size (Chapter III. section A.; page 776, "size D") characteristics; (b) defining respective regions of specified extent within the image around respective said locations (Chapter III. section A.; page 776, "mark a spot"); (c) deriving from the data within respective said regions one or more respective closed contours comprising points of equal intensities (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function" and "Gaussian function is a type of a probability density function"). However, all the claim limitations are not disclosed by Netsch. However, Madachy discloses using a computer or processor for performing (METHOD, page 373, "Gould/Denaza IP8500 image processor on a VAX host") and (d) estimating the curvature of at least one respective said contour within respective said regions and producing a measure of any concavity thereof (SHAPE, pages 373, "R(i)" and "curvature").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Madachy's method in Netsch's method to provide automated detection of microcalcifications as suggested by Netsch (abstract).

Regarding claim 2, Madachy teaches all the previous claim limitation except the one specified in claim 2. However, Netsch teaches wherein step (a) comprising the

application of a radially-symmetric difference filter with zero mean (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function").

Regarding claim 3, Netch further teaches the image is filtered at a plurality of resolutions of increasing scale (Figure 4; section III. A Motivation and Outline; pages 776-777, "scales $h=1$, ...").

Regarding claim 4, Netch further teaches locations are identified in accordance with the locations of respective local extrema (abstract, "local maxima") in the output of said filter (abstract, "possible locations of ... local maxima ... filtered image ...").

Regarding claim 5, Netch further teaches including the step of sorting, in order of intensity (section III A. Motivations and Outline, "range of scales"), local extrema (section III A. Motivations and Outline, "local maxima") in the output of said filter (abstract, "possible locations of ... local maxima ... filtered image ...") and selecting for further analysis only those objects which correspond to a specified proportion of said extrema in such order (section III A. Motivations and Outline, "Detection ... filter ... threshold").

Regarding claim 6, Madachy further discloses following step (a): selecting an intensity threshold (TEXTURE, pages 373, "15%") related to the mean intensity of pixels (TEXTURE, pages 373, "mean value") within the image in neighbourhoods of said locations (TEXTURE, page 373); creating a binary image according to whether pixels in the first-mentioned image (Figure 2; TEXTURE, pages 373) are above or below said threshold (TEXTURE, pages 373, "15%"); identifying regions in the binary image

composed of connected pixels which are below said threshold in the first-mentioned image (Figure 2; TEXTURE, page 373, "white pixels"); and rejecting from further analysis those objects which correspond to such regions in the binary image which fall below a specified size or thickness (TEXTURE, page 373, "larger than ..").

Regarding claim 7, Madachy further teaches wherein step (c) comprises, for respective said regions (TEXTURE, page 373, "subregions") deriving respective first (Figure 2; TEXTURE, page 373, "white pixel region") and second said contours (TEXTURE, page 373, "black pixel region") having respectively lower (TEXTURE, page 373, "optical density being 15% lower than mean value") and higher resolutions (TEXTURE, page 373, "optical density being 15% greater than mean value"), determining whether the sizes and locations of said first and second contours are consistent within specified criteria and, if so consistent, selecting said second contour for step (d) (TEXTURE, page 373, "the black and white regions are ... regions larger than 2 ... operation.").

Regarding claim 8, Madachy further teaches the first said contour is derived by: seeking within the region one or more contours of respective specified intensities (Figure 2; TEXTURE, page 373, "white pixel region" and "black pixel region"); determining whether the or each such contour is a closed contour and meets specified location, size and/or intensity orientation criteria (METHOD, "continuous contours ... fixed size"; TEXTURE, page 373, "the black and white regions are ... regions larger than 2 ... operation."); and if more than one such contour is a closed contour and meets

such criteria, selecting from the same the contour of the lowest intensity (Figure 2; TEXTURE, page 373, "white pixel region").

Regarding claim 9, Madachy further teaches wherein said specified intensities (Figure 2; TEXTURE, page 373, "white pixel region") are no greater than that which corresponds to the contour of highest edge strength within the respective region (TEXTURE, page 373, "black pixel region").

Regarding claim 10, Netch further teaches wherein step (a) comprising the application of a radially-symmetric difference filter with zero mean (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function") and said first contour is derived by seeking one or more contours in the output of said filter for the respective region and said specified intensities are no greater than the zero level in such output (Figs. 3-5; equations (1)-(6); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function").

Regarding claim 11, Madachy further discloses the second said contour is derived by: seeking within the region a plurality of contours of respective specified intensities ranging between the lowest and highest intensities within the region (Figure 2; TEXTURE, page 373, "white pixel region" and "black pixel region"); determining whether each such contour is a closed contour and meets specified location, size and/or intensity orientation criteria (METHOD, "continuous contours ... fixed size"; TEXTURE, page 373, "the black and white regions are ... regions larger than 2 ... operation."); and if more than one such contour is a closed contour and meets such criteria, selecting

from the same the contour having the highest edge strength (Figure 2; TEXTURE, page 373, "white pixel region").

Regarding claim 12, Netch further teaches step (d) including the application of a Probability Density Association Filter to respective said contours (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function" and "Gaussian function is a type of a probability density function").

Regarding claim 13, Netch further teaches step (d) comprising, for respective said contours (III D. Feature Estimation by Signatures; pages 778, "cylinder"): measuring the curvature of the contour at a plurality of points around the contour, convexity and concavity being of opposite sign (equation (7); III D. Feature Estimation by Signatures; pages 778, "cylinder"); setting convex values of such curvature to zero (equation (7); III D. Feature Estimation by Signatures; pages 778, "cylinder"); plotting resultant values of curvature at said points against a measure of the distance of the respective point along the contour (Figs. 7-10); and computing as said measure of concavity the line integral of such plot (equations (7)-(16)).

Regarding claim 14, Madachy further discloses further comprising the step of: (e) classifying objects into one of at least two classes (CELL CLASSIFICATION, page 373, "parameters") in accordance with a function of said measure of concavity of a contour (SHAPE, page 373, "R(i)") corresponding to the respective object and a measure of the mean intensity (TEXTURE, page 373, "mean value") of the respective object.

Regarding claim 17, Madachy further discloses further comprising the step of: (f) counting the number of objects classified into a specified one of said classes (PREVIOUS EFFORTS, page 372, "counted mitoses in breast cancer ...").

Regarding claim 18, Madachy further discloses wherein the image is of a histological or cytology specimen or of a soil sample (INTRODUCTION, page 372, "pre-scored specimens").

Regarding claim 20, Madachy further discloses the image being of a section of breast tissue and said specified class is identified as the class of mitotic epithelial cell nuclei (PREVIOUS EFFORT, page 372, "counted mitoses in breast cancer ...").

Regarding claim 22, Netsch discloses a method for the automated identification of mitotic activity from a digital image of a histological specimen, including the steps of: (a) identifying the locations of objects (Chapter III. section A.; page 776, "circular spots") within the image which objects have specified intensity (Chapter III. section A.; page 776, "local contrast C") and size (Chapter III. section A.; page 776, "size D") characteristics associated with epithelial cell nuclei (Fig. 6; Chapter I, "Breast cancer"); (b) defining regions of specified extent within the image which contain respective said objects (Chapter III. section A.; page 776, "mark a spot"); (c) deriving from the data within respective said regions one or more respective closed contours comprising points of equal intensities (Fig. 3; equations (1)-(4); section III. A. Motivation and Outline, page 776, "circularly-symmetric Gaussian function" and "Gaussian function is a type of a probability density function"); All of the claim limitations are not disclosed by Netsch. However, Madachy discloses using a computer or processor for performing (METHOD,

page 373, "Gould/Denaza IP8500 image processor on a VAX host"), (d) estimating the curvature of at least one respective said contour within respective said regions at least to produce a measure of any concavity thereof (SHAPE, pages 373, "R(i)" and "curvature") and (e) classifying objects as representing mitotic cell nuclei as a function of at least said measure of concavity of a contour corresponding to the respective object (TABLES 1 and 2; page 374, "parameter statistics" and "classification").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Madachy's method in Metch's method to provide automated detection of microcalcifications as suggested by Netch (abstract).

Regarding claim 25, Madachy further discloses a computer program comprising instructions to cause a computer to execute a method (METHOD, page 373, "Gould/Denaza IP8500 image processor on a VAX host"). Rest of the claim limitations are analogous and correspond to claim 1. See rejection of claim 1 for further explanation.

Regarding claim 26, Madachy further discloses a diagnostic report produced by method according to claim 1 (page 374, TABLE 1 and TABLE 2).

Regarding claim 27, Madachy further discloses a diagnostic report produced by method according to claim 22 (page 374, TABLE 1 and TABLE 2).

12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Netsch et al. ("Scale-Space Signatures for the Detection Clustered Microclacifications in Digital Mammograms") in view of Soni et al. (US 5,363,850).

Regarding claim 15, Netsch teaches all the previous claim limitation except the one specified in claim 15. However, Soni discloses using a Fisher classifier (claims 5 and 6, "Fisher classification").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Soni's invention in Netsch's method to provide high resolution as suggested by Soni (col. 1, lines 8-10).

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Netsch et al. ("Scale-Space Signatures for the Detection Clustered Microclacifications in Digital Mammograms") in view of DeLong (US 2002/0012466).

Regarding claim 16, Netsch teaches all the previous claim limitation except the one specified in claim 16. However, DeLong discloses the intensities of respective objects are normalised prior to step (e) (Fig. 2; claim 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use DeLong's invention in Netsch's method to provide an image analysis process which can cyclicly and interactively approximate the wished and ideas of a user without the user having to have detailed knowledge of the image processing itself (paragraph [0006]).

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN Wahnkyo LEE whose telephone number is (571)272-9554. The examiner can normally be reached on Monday - Friday (Alt.) 7:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Samir Ahmed can be reached on (571) 272-7413. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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/John Wahnkyo Lee/
Examiner, Art Unit 2624

/Samir A. Ahmed/

Supervisory Patent Examiner, Art Unit 2624